**Premarket Notification [510(k)] Summary**

OCT 16 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K092570

**Company:** Horiba ABX SAS
Parc Euromédecine
Rue du Caducée – BP 7290
34184 Montpellier cedex 4
FRANCE
Telephone: + (33) 4 67 14 18 43
Fax: + (33) 4 67 14 18 75

Contact Person: Caroline Ferrer (caroline.ferrer@horiba.com)

Date Prepared: 11th August 2009

**Device Name:**
The following calibrator is for use in conjunction with the ABX PENTRA 400, cleared to market under K052007.

CALIBRATOR:

| | |
|---|---|
| Trade/Proprietary Name: | **ABX PENTRA TPU Cal** |
| Common or Usual Name: | Urine calibrator |
| Device Class | Class II |
| Classification Name: | §862.1150 : Calibrator |
| Product Code: | JIT ; Calibrator, Secondary |

**Substantial Equivalence:**

The data and information supplied in this submission demonstrates substantial equivalence to the predicate device:

| **Submission device** | **Substantially equivalent Predicate device** |
|---|---|
| ABX PENTRA TPU Cal<br>Horiba ABX SAS | ABX PENTRA Urine Cal<br>Horiba ABX SAS<br>K071779 |

**Description:**

The calibrator included in this submission is for use on the **ABX PENTRA 400** (K052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The **ABX PENTRA TPU Cal** is a liquid calibrator based on a buffered aqueous solution, containing human serum. The assigned values of the calibrator components are given on the calibrator vials, ensuring optimal calibration of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer. This calibrator is provided in three vials of 3 ml.

**Intended Use:**

ABX Pentra TPU Cal is used to calibrate total proteins in urine measurement with reagent ABX Pentra Urinary Proteins CP on ABX PENTRA 400 analyzer.

**CALIBRATOR**

| **ABX PENTRA TPU Cal:** | |
|---|---|
| Analytes | Total Proteins in urine |
| Format | Liquid with chemical additives and materials of biological origin |
| Stability | Closed stability: 24 months at 2-8°C<br>Open stability: 9 weeks at 2-8°C |

**Conclusions for Performance Testing :**
The performance testing data conclude that the safety and effectiveness of the device are not compromised, and that they met all acceptance criteria, demonstrating that the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Horiba ABX SAS, Inc.
c/o Ms. Caroline Ferrer
Regulatory Affairs Specialist
Parc Euromedecine Rue Du Caducee,
BP 7290
34184 Montpellier Cedex 4, France

OCT 16 2009

Re: k092570
Trade Name: ABX PENTRA TPU Cal
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIT
Dated: August 18, 2009
Received: August 21, 2009

Dear Ms. Ferrer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indication for Use

510(k) Number (if known): K092570

Device Name: ABX PENTRA TPU Cal

Indication For Use:

The ABX PENTRA Urine Cal is a calibrator for use in the calibration of the quantitative method : ABX PENTRA Urinary Proteins CP on ABX PENTRA 400 clinical chemistry analyzer as specified on the vials.

Prescription Use ___X___ And/Or Over the Counter Use ____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092570